

Remarks

I. Status of the Claims

Upon entry of the foregoing amendments, claims 27, 36, 37, 39, 44-47, 70, 72 and 92-103 are pending in the application, with claims 27, 37 and 39 being the independent claims. Claims 29-35, 40-43, 48-55, 60-69, 71 and 96-99 are sought to be canceled without prejudice or disclaimer of the subject matter therein. Claims 27, 36, 37, 39, 44-47, 70 and 95 have been amended to clarify the subject matter being claimed and to correct the dependency of the claims. New claims 100-103 are sought to be added to expand the embodiments of the elected subject matter. Support for the amendments may be found, for example, at page 7, lines 1-2 and 30-31, page 9, lines 4-13, page 17, lines 22-29, page 19, lines 20-31 and page 20, lines 1-31 and in original claims 4, 32 and 33. These changes are believed to introduce no new matter, and their entry is respectfully requested.

II. Summary of the Office Action

In the Office Action dated June 4, 2002, the Examiner has made the Restriction Requirement final and has made five rejections of the claims. Applicants respectfully offer the following remarks to overcome or traverse each element of these rejections in the Office Action.

III. The Rejections Under 35 U.S.C. § 112, Second Paragraph, Are Traversed

In the Office Action at pages 3 and 4, the Examiner has rejected claims 27, 36, 70, 72 and 92-95 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. Applicants respectfully traverse these rejections.

A. The Rejection of Claim 27

In the Office Action at page 3, the Examiner has rejected claim 27 under 35 U.S.C. § 112, second paragraph for alleged uncertainty concerning the metes and bounds of the claim. The alleged ground for the rejection is that it is unclear whether the invention is directed to a nutritive medium powder that consists of dried eukaryotic cells or is for the culture or growth of eukaryotic cells.

The present claim is directed to a eukaryotic cell culture medium powder. The powder can be used to maintain or promote the growth or proliferation of cells. Hence, the metes and bounds of the claim are clearly defined.

B. The First Rejection of Claim 36

In the Office Action at page 3, the Examiner has rejected claim 36 under 35 U.S.C. § 112, second paragraph for allegedly lacking clear antecedent basis. According to the Examiner, Applicants may overcome the rejection by inserting the term "eukaryotic" in the claim. Amended claim 36 provides clear antecedent basis from the claims from which it depends.

C. *The Second Rejection of Claim 36*

In the Office Action at pages 3 and 4, the Examiner has rejected claim 36 under 35 U.S.C. § 112, second paragraph for allegedly being uncertain with respect to the phrase "wherein said nutritive medium has a pH of between 7.1 and 7.5 when said medium is reconstituted with a solvent."

The pH value of the cell culture medium is clearly set forth in the present claim as being between 7.1 and 7.5 when the medium is reconstituted with a solvent, wherein said solvent is water or serum. As set forth in newly added claims 100-102 and as disclosed in the specification at page 20, line 13 to page 21, line 5, one or more buffer salts or agents such as an acid or a base, may be added to the powdered medium. Upon reconstitution with water or serum, the pH is optimal for support of cell cultivation or growth without a need for adjustment of the pH of the liquid medium. Those buffering salts and/or acids or bases, in combination with water or serum, that do not produce a cell culture medium with a pH between 7.1 and 7.5 fall outside the scope of the claim. One of ordinary skill in the art would readily recognize the metes and bounds of the claim. Hence, the claim is not indefinite.

D. *The First Rejection of Claim 95*

In the Office Action at page 4, the Examiner has rejected claim 95 for allegedly depending from itself. Amended claim 95 properly depends from claims 93-94.

E. The Second Rejection of Claim 95

In the Office Action at page 4, the Examiner has rejected claim 95 for allegedly lacking clear antecedent basis. The Examiner states that the rejection may be overcome by replacing the phrase "wherein the medium powder is not agglomerated" with the phrase "wherein the non-agglomerated medium powder." The claim has been amended in the manner suggested by the Examiner.

F. Summary

In view of the foregoing remarks, Applicants respectfully submit that claims 27, 36, 70, 72 and 92-95, as currently presented, particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Therefore, reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, is respectfully requested.

IV. The Rejection under 35 U.S.C. § 102(b) over Pisecky et al. (AC1)

Claims 27, 36, 37, 39 and 47 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Pisecky *et al.* (AC1). Applicants respectfully traverse this rejection.

The present claims are drawn to an agglomerated eukaryotic cell culture medium powder. Pisecky *et al.* is alleged to disclose a process for producing an agglomerated powdery milk product that is suitable for food and fodder consumption. *See* Office Action, page 5, lines 8-9. Milk products are inappropriate for culture of eukaryotic cells. In fact, the disclosure of Pisecky *et al.* has been asserted by the Examiner to be appropriate for food and fodder consumption and has been interpreted to be read as a

nutritive medium powder, rather than an agglomerated medium for the culture of eukaryotic cells. Hence, Pisecky *et al.* cannot anticipate the present claims which are directed to an agglomerated eukaryotic cell culture medium.

Reconsideration and withdrawal of the rejection is respectfully requested.

V. *The Rejection under 35 U.S.C. § 102(b) over Peebles (A) and Getler et al. (N) as evidenced by Hup et al. (B)*

Claims 27, 36, 37, 47 and 92-95 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Peebles (A) and Getler *et al.* (N) as evidenced by the teachings of Hup *et al.* (B). Applicants respectfully traverse this rejection.

The present claims are drawn to an agglomerated eukaryotic cell culture medium powder. Peebles and Getler *et al.* disclose dried or agglomerated milk products. Hup *et al.* is offered for the proposition that bacterial cell cultures can be sustained in starter cultures and fermented milk products. As stated *supra* in item IV, dried milk products are inappropriate for culture of eukaryotic cells. The present claims do not encompass media for the culture of non-eukaryotic cells. Therefore, the present claims are not anticipated by the cited references.

Reconsideration and withdrawal of the rejection is respectfully requested.

VI. *The Rejection under 35 U.S.C. § 102(b) over Robey et al. (AT4) and Camire et al (AR1)*

Claims 37, 39 and 44-46 are rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Robey *et al.* (AT4) and Camire *et al.* (AR1). Applicants respectfully traverse this rejection.

The present claims are drawn to an agglomerated eukaryotic cell culture medium powder. Robey *et al.* disclose a spray dry process for fetal bovine serum and Camire *et al.* disclose a powdered fetal bovine serum for cell culture. *See* abstracts of both references. Neither reference discloses an agglomerated eukaryotic cell culture medium, as is required by the present claims. Under 35 U.S.C. § 102, a claim can only be anticipated if every element in the claim is expressly or inherently disclosed in a single prior art reference. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984). In addition, a claim can only be anticipated by a publication if the publication describes the claimed invention with sufficient enabling detail to place the public in possession of the invention. *See In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985); *see also PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996) (“To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter.”). The references cited by the Examiner do not disclose every element of the claim, nor do they provide sufficient enabling detail to place the public in possession of the presently claimed invention. Therefore, the cited references cannot anticipate the claimed subject matter.

The powdered fetal bovine serum disclosed by Robey *et al.* and Camire *et al.* are distinctly different from the presently claimed agglomerated eukaryotic cell culture medium powders. Powdered media produced by spray-drying, for example, have distinct disadvantages. *See* specification at page 5, lines 19-32. Powdered media can become insoluble or aggregate such that resolubilization is difficult or impossible. Powdered media can also have fine dust particles that can become airborne, which results in a loss of material. In addition, such fine dust particles are problematic in biotechnology production facilities.

Agglomerated powders avoid the aforementioned difficulties. In particular, the agglomerated powder has a larger particle size than the unagglomerated powder, which reduces the dusting problem. *See* specification at page 26, lines 15-17. Further, the agglomerated powder exhibits more rapid dissolution than non-agglomerated powder media. *See* specification at page 54, Example 10. Hence, the present invention is clearly distinct from the powdered fetal bovine serum cited in this rejection.

Reconsideration and withdrawal of the rejection is respectfully requested.

VII. *The Rejection under 35 U.S.C. § 103(a) over over Peebles (A) and Getler et al. (N), Robey et al. (AT4) and Camire et al. (AR1) in view of DiSorbo et al. (AG2)*

Claims 27, 36, 37, 39, 44-47, 70, 72 and 92-95 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Peebles (A), Getler *et al.* (N), Robey *et al.* (AT4) and Camire *et al.* (AR1) in view of DiSorbo *et al.* (AG2). Applicants respectfully traverse this rejection.

The disclosures and deficiencies of Peebles, Getler *et al.*, Robey *et al.* and Camire *et al.*, as applied to the present claims, have been discussed *supra* in items V and VI. The present claims are drawn to an agglomerated eukaryotic cell culture medium powder. Dry milk products are inappropriate for the culture of eukaryotic cells. Further, Robey *et al.* and Camire *et al.* particularly do not disclose an agglomerated eukaryotic cell culture medium powder. Hence, Peebles, Getler *et al.*, Robey *et al.* and Camire *et al.* are deficient as primary references for establishing a *prima facie* case of obviousness.

The deficiencies of Peebles, Getler *et al.*, Robey *et al.* and Camire *et al.* are not cured by DiSorbo *et al.* DiSorbo *et al.*, as noted by the Examiner, merely discloses a kit comprising one or more containers containing media and solvents. *See* Office Action at pages 9 and 10. Hence, the combined disclosures of Peebles, Getler *et al.*, Robey *et al.* and Camire *et al.* in view of DiSorbo *et al.* do not disclose or suggest the presently claimed invention. Therefore, the burden required to formulate a *prima facie* case of obviousness of the invention as presently claimed has not been satisfied.

Reconsideration and withdrawal of the rejection is respectfully requested.

Conclusion

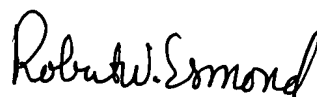
All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for

allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Robert W. Esmond
Attorney for Applicants
Registration No. 32,893

Date: Nov. 4, 2002
1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600

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Version with markings to show changes made

In the Claims:

Claims 29-35, 40-43, 48-55, 60-69, 71 and 96-99 are sought to be canceled.

Claims 27, 36, 37, 39, 44-47, 70 and 95 are amended as follows:

27. (Thrice amended) [A] An agglomerated eukaryotic [nutritive] cell culture medium powder prepared by agglomerating a dry powder eukaryotic [nutritive] cell culture medium with a solvent.

36. (Twice amended) The agglomerated eukaryotic cell culture [nutritive] medium powder of any one of claims 27 and 100-102 [29-31], wherein said [nutritive] eukaryotic cell culture medium has a pH of between 7.1-7.5 when said medium is reconstituted with a solvent, wherein said solvent is water or serum.

37. (Twice amended) [A nutritive] An agglomerated eukaryotic cell culture medium supplement powder prepared by agglomerating a dry powder [nutritive] eukaryotic cell culture medium supplement with a solvent.

39. (Twice amended) [A nutritive] An agglomerated eukaryotic cell culture medium subgroup powder prepared by agglomerating a dry powder [nutritive] eukaryotic cell culture medium subgroup with a solvent.

44. (Twice amended) The [nutritive] agglomerated eukaryotic cell culture medium supplement powder of claim 37, wherein said [nutritive] dry powder eukaryotic cell culture medium supplement is serum.

45. (Once amended) The [nutritive] agglomerated eukaryotic cell culture medium supplement powder of claim 44, wherein said serum is bovine serum or human serum.

46. (Once amended) The [nutritive] agglomerated eukaryotic cell culture medium supplement powder of claim 45, wherein said bovine serum is fetal bovine serum or calf serum.

47. (Twice amended) The [nutritive] agglomerated eukaryotic cell culture medium supplement powder of claim 37, wherein said [nutritive] eukaryotic cell culture medium supplement powder comprises one or more nutritive medium components.

70. (Thrice amended) A kit for use in the cultivation of a cell, said kit comprising one or more containers wherein a first container contains the powder of any one of claims 27, [29-31, 37, 39-43] 36, 37, 39, 44-47, 92-95 and [60] 100-104.

95. (Once Amended) The medium powder of any one of claims [93-95] 93-94, wherein the non-agglomerated medium powder [that is not agglomerated] is a lyophilized or ball-milled powder.

Please add new claims 100-103.